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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,046	07/06/2001	Geert Maertens	2752-51	7316

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EXAMINER	
WORTMAN, DONNA C	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,046	MAERTENS ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *24-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group I, claims 25-44, insofar as drawn to antibody recognizing HCV type 3 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that all four groups as set out in Paper No. 9 are classified in the same class and subclass and therefore are not recognized as defining separately patentable subject matter and that searching the same class/subclass would not require an undue burden for the Examiner. This is not found persuasive because each invention requires a separate search even though antibodies to different types of viruses, e.g., may be classified in the same class and subclass; searching and examining multiple inventions in one application would constitute a burden on the Office. Further, Applicant's argument that inventions in the same class and subclass are not recognized as separately patentable subject matter is not understood inasmuch as it would appear that Applicant intends to argue that each patent class and subclass can support only one patentable invention, and that every invention after the earliest patented invention classified in a given class/subclass would be unpatentable over the first one.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 08/362455 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers.

Claims 24-44 are under examination insofar as each is drawn to an antibody that specifically recognizes an antigen from HCV type 3.

This application is not in complete compliance with the sequence rules, 37 CFR 1.821-1.825. In particular, at least Table 6 on page 70 discloses sequences without accompanying SEQ ID NO's as required by 37 CFR 1.821(d).

The disclosure is objected to because of the following informalities:

The disclosure does not have a section headed "BRIEF DESCRIPTION OF THE DRAWINGS."

Appropriate correction is required.

Claims 24, 26, and 30-32 are objected to because of the following informalities:

In claim 24, "A HCV antibody ..." should read "An HCV antibody ...". Appropriate correction is required.

In claim 26, "claims" should read "claim."

Claim 26 lacks a period at the end of the claim.

In claim 30, "claims" should read "claim."

In claim 31, "claims" should read "claim."

In claim 32, "claims" should read "claim."

Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 40, drawn to a

humanized antibody of claim 33, does not further limit the subject matter of claim 33 because claim 33 also recites a humanized antibody.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 37, 38, 40, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for humanized monoclonal antibodies, does not reasonably provide enablement for humanized antibodies as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification at page 43 indicates that monoclonal antibodies may be humanized but does not disclose the humanization of polyclonal antisera or how to make humanized polyclonal antibodies, although polyclonal antibodies are encompassed by claims 33, 37, 38, 40, 43 and 44. As an indication of the state of the art at the time the invention was made, Co. et al. (Proc. Natl. Acad. Sci. 88(7):2869-2973, 1991), cited on PTO 892, attached, teach how to make humanized individual monoclonal antibodies was known but do not teach how to humanize antisera. Lacking specific guidance from Applicant, and taking into account the state of the art at the time the invention was made, it would require undue experimentation for one of skill in the art at the time the invention was made to make and use other than humanized monoclonal antibodies against HCV type 3.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 25 are indefinite for reciting material other than the elected invention.

Claim 24 is indefinite insofar as it recites "A(n) HCV antibody specifically recognizing an antigen from type 3 of HCV" since it is not clear what degree of specificity is required in order to meet the intended claim limitations. For example, would any anti-HCV antibody that binds to an antigen that occurs in type 3 HCV, even if it cross-reacts to some extent with an antigen from one or more of the other HCV types be included, or is it intended to claim an antibody that binds only to an HCV type 3 antigen and does not bind to any antigen from another HCV type?

Claim 34 is indefinite because it is a dependent claim that recites "according to any of claim 26," which phrase is unclear.

Claim 36 is indefinite because it is a dependent claim that recites "according to any of claim 26," which phrase is unclear.

Claim 37 is indefinite because it is a dependent claim that recites "according to any of claim 33," which phrase is unclear.

Claim 39 is indefinite because it is a dependent claim that recites "according to any of claim 26," which phrase is unclear.

Claim 40 is indefinite because it is a dependent claim that recites "according to any of claims 33," which phrase is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24, 25, 27, 28, 30, 31 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/19743, Cha et al., in light of Applicant's admission in the specification at Table 3, page 11. Cha et al. disclose nucleic acid sequences 20-22, 29-31, 48, 49 from HCV type GIV (see, e.g., Fig. 2a-2e; Fig. 3; Fig. 4d) and teach using

the disclosed nucleic acid sequences to produce peptides as well as antibodies directed to the peptides for use in kits and assays for detecting HCV of the corresponding genotype (see, e.g., "Peptide and antibody composition," pages 13-17). Although Cha et al. do not refer to any of the disclosed HCV types as "type 3," the instant specification at Table 3, page 11, indicates that Cha's type GIV corresponds to Applicant's type 3. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have produced and used antibodies directed to HCV type 3 because Cha et al. teach sequences of HCV GIV, which is the same as HCV type 3, and suggest doing making and using antibodies against HCV GIV for use in diagnostics and treatments.

Claims 26, 29, 32, 35, 36, 41 and 42 and claims 34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al., in light of Applicant's admission in the specification, as applied above, in view of Co$_{\text{q}}$ et al., cited on PTO 892, attached. With respect to claims 26, 29, 32, 35, 36, 41 and 42, while Cha et al. disclose antibodies raised against HCV type 3 peptides that would specifically detect that viral type, Cha et al. do not specifically disclose antiviral monoclonal antibodies. Co et al. teach that monoclonal antibodies against viral antigens are generally known, advantageous, and useful (see, e.g., page 2869, Abstract and first text paragraph). It would have been obvious to one of ordinary skill in the art to have made monoclonal antibodies as taught by Co et al. to the HCV type 3 viral antigens of Cha et al. because Co et al. disclose that antiviral monoclonal antibodies have wide applications and because monoclonal antibodies bind to a single epitope and thus each has unique specificity. With respect to claims 34, 38 and 39, Co. et al. additionally teach the advantages of making

humanized antiviral monoclonal antibodies, i.e., humanized antibodies intended for use in antiviral therapy have reduced potential for causing an immune response in a human patient. It would have been obvious to one of ordinary skill in the art to have followed the teachings of Co. et al. and to have made humanized antiviral monoclonal antibodies against HCV type 3 of Cha et al. in order to obtain anti-HCV type 3 antibodies with reduced immunogenicity for human therapeutic use against HCV type 3.

Applicant will note that certain documents on PTO 1449 filed on 7/06/01 have not been initialed since no copies could be located. If Applicant wishes to supply the missing references, they will be considered as if supplied when the PTO 1449 was filed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032 until 08 January 2004 and 571-272-0913 after that date. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027 until 26 January 2004 and 571-272-0902 after that date. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw